

Roadmap for Research Activities at RSJH

	Phase 0	Phase 1	Phase 2	Phase 3
Description	Most Research Activity Suspended Other Than COVID-19 Studies	Slow Ramp Up of Research Activity	Increased Research Activity and Clinical Foot Traffic	Additional Research Visits Acceptable
Health and Safety	Follow SJHH COVID-19 Staff and Patient Safety Guidelines	Follow SJHH COVID-19 Staff and Patient Safety Guidelines	Follow SJHH COVID-19 Staff and Patient Safety Guidelines	Follow SJHH COVID-19 Staff and Patient Safety Guidelines
Study Criteria	<p>Most studies suspended, other than COVID-19 studies, or in cases where access to a research agent is the patient's only option.</p> <p>Suspended studies must be assessed by the Principal Investigator for viability to continue in upcoming Phases.</p>	<p>Studies must meet the following criteria:</p> <p>1. Remotely conducted:</p> <ul style="list-style-type: none"> No additional research employee traffic at clinical sites. No additional research participant traffic at clinical sites. All regulatory, contract and ethics approvals in place <p>2. Recruiting in-hospital patients or patients who are visiting clinics:</p> <ul style="list-style-type: none"> Patients are already in the hospital, or are coming into the hospital for a scheduled clinical visit. There is no increased draw on clinical services required, other than what the patient would receive if he/she followed the non-research care pathway. 	<p>Studies must meet the following criteria:</p> <p>1. The studies that meet the criteria specified in Phase 1.</p> <p>2. Recruiting in-hospital patients or patients who are visiting clinics:</p> <ul style="list-style-type: none"> If there is a research study that does impact clinical services beyond standard of care, it still must be approved in advance by the impacted area. Follow-up visits still done virtually All regulatory, contract, and ethics approvals in place 	<p>Studies must meet the following criteria:</p> <p>1. The studies that meet the criteria specified in Phase 1 and Phase 2.</p> <p>New to Phase 3:</p> <p>Additional research visits acceptable (i.e., outside of regularly scheduled clinical visits.)</p> <p>"Healthy Volunteers" allowed on site.</p>

Phase 0



Phase 1



Phase 2



Phase 3

Study Criteria
(continued)

- If there is a research study that does impact clinical services beyond standard of care, it must be approved in advance by the impacted area and Principal Investigators must arrange precise timetabling with the relevant clinical unit.
- No additional research employee traffic at clinical sites.
- Follow-up visits done virtually.
- All regulatory, contract, and ethics approvals in place

Exceptions may be approved in consultation with the SJHH VP Research/Scientific Director and/or Executive Director. *

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RSJH Administration continues to track Research Activity.



Engaging
Research Participants

Access to all clinical areas restricted.

Only approved COVID-19 related projects OR studies where the research agent is the patient's only option can continue, with appropriate safety and screening precautions according to SJHH COVID-19 guidelines

Maintain physical and social distancing measures through:

- Remote engagement of participants
- Only engaging patients already in hospital / coming in for a clinical visit
- Keep research activity confined to clinical research areas.
- All site-screening measures apply.

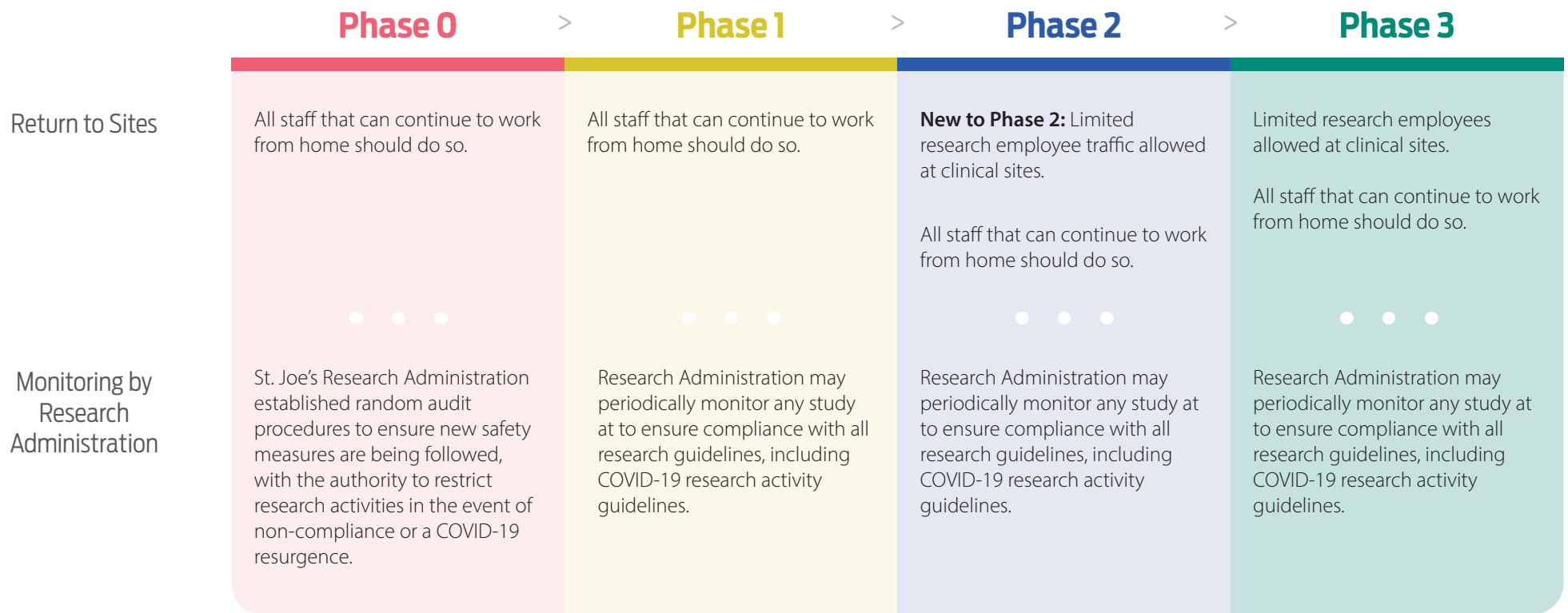
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- Remote engagement of participants
- Engaging patients already in hospital / coming in for a clinical visit
- Healthy Volunteers can come on site.
- Additional research visits outside of the standard of care pathway allowed.





RSJH Administration Team will modify criteria and recommendations based on COVID-19 situation.

*VP Research/Scientific Director and/or RSJH Executive Director. To enable coordination and prioritization of clinical resources for research purposes, will review and approve any exceptions to the above Phases.

Applying for On-Site Visits of Study Monitors, Study Sponsors, and Research-Only Participants (Phase 3):

1

Submit your on-site study application using the online portal.

Access the online portal at rsjh.ca/ONSITE or from the COVID-19 Research Updates webpage.

2

Once approved, a unique link will be emailed to you. Use this link to request on-site visits associated with your study.

This includes study monitors, study sponsors, and research-only participants (non-clinical).

3

Researchers will receive a letter via email for each approved on-site visitor.

Each letter grants access to the hospital on a specific date and time for a named individual.